

## Meeting Notes: EPA & Color Pigments Manufacturers Association (CPMA) Meeting on Pigment Violet 29

Meeting Time /Date /Location	
Date	2/13/2017
Time/Location	1:30 – 3:00 pm (EST)/1201 Constitution Ave NW, Room 4140
Dial-in	1-(866)-299-3188
Meeting ID	202-564-0341

### Agenda:

Introductions  
Work Plan Methodology and Screening Purposes  
Toxicological Properties of Pigment Violet 29  
Information to be Used in Scoping  
Uses of Pigment Violet 29  
Follow Up/Next Steps

### Meeting Attendees:

#### **CPMA and Company:**

Robert Mott, Sun Chemical  
Steve Camenisch, BASF Colors & Effects  
Dave Wawer, CPMA Executive Director  
Jamie Conrad, CPMA Agency Counsel  
Dan Newton, SOCMA GR  
Glenn Merritt, CPMA Issues Counsel

#### **EPA:**

Joel Wolf, CCD  
Doug Parsons, CCD  
Niva Kramek, CCD  
Alie Muneer, RAD  
Tala Henry, RAD  
Jafrul Hasan, RAD  
Hannah Braun, CCD  
Loraine Passe, CCD  
Eileen Sheehan, CCD

### Work Plan Methodology and Screening Processes:

**Joel Wolf:** EPA has been meeting with stakeholders to discuss uses and conditions of use of the first ten chemicals to be evaluated under TSCA reform. This information has been gathered into dossiers that are currently available for informal comment. This meeting is to discuss EPA's scoping process and path moving forward concerning the risk evaluation as well as to gather additional use information on Pigment Violet 29. Hannah Braun is the lead for the Pigment Violet dossier and will explain where EPA is in the process.

**Tala Henry:** This meeting is different than some of the previous stakeholder meetings that EPA has conducted because EPA met with CPMA in December to discuss the Pigment Violet, specifically the rationale for its inclusion in the First 10 chemicals to undergo risk evaluation. As follow-up, today, EPA will explain the data and information used that resulted in Pigment Violet 29 being included on the 2014 Work Plan and also what existing test data EPA has subsequently identified that could be useful for risk evaluation. However, the main focus of the meeting today is to discuss uses and conditions of use as described by Joel Wolf..

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## Toxicological Properties of Pigment Violet 29:

**Hannah Braun:** In 2012, EPA scored and sorted chemicals based on exposure, hazard, and persistence and accumulation on a scale of 1-3. Pigment Violet 29 was originally given a hazard score of 3 due to high aquatic toxicity, an exposure score of 3 due to consumer use, and a persistence and accumulation score of 2. TSCA was updated in 2014 to incorporate new CDR information into exposure scores for the chemicals; however, the exposure score for Violet 29 remained a 3.

**Alie Muneer:** The hazard data used in the 2012 hazard scoring was a QSAR estimate identified in the 2012 Ecological Categorization Results, 2012 Canadian Domestic Substances List (DSL); this estimate was from EPA's ASTER expert system. The QSAR estimate was an acute fish toxicity test LC<sub>50</sub> value of 4.62097 mg/L, which falls within the high hazard range of <1.0-10 mg/L; therefore, it was identified as of high hazard concern in the EPA methods. The hazard scores were not updated during the 2014 TSCA workplan update. During previous efforts to scope a risk assessment for Pigment Violet 29, EPA identified a suite of test data that was submitted under REACH, including an acute aquatic toxicity base set showing no effects at saturation for all species tested. Hence, the hazard, based on empirical data, may be lower than the initial score indicated in the TSCA workplan. However, EPA needs to see the test reports in order to review and evaluate the studies and confirm the hazard of Pigment Violet 29.

## Information to be Used in Scoping:

**Tala Henry:** The 2012 workplan analyzes a variety of sources that are articulated in the methodology document. The data that showed toxicity to fish and other aquatic organisms came from a Canadian Report that cited EPA's ASTER (Assessment Tools for the Evaluation of Risk) system as the source of the acute aquatic toxicity estimate.

**Glenn Meritt, CPMA:** That Canadian assessment was subsequently changed to reflect lower toxicity.

**Tala Henry:** That is consistent with EPA's findings, but we need to receive the study reports to review and confirm what has been reported under REACH. EPA cannot rely on a secondary database or the robust summaries that we have identified. In the screening stage, EPA was looking at any and all available information. We can see that this information is available through the ECHA database, but we would need to review the lab study reports to make conclusions on aquatic hazards.

**Jamie Conrad, CPMA:** The process of a risk evaluation starts as a clean slate assessing all potential hazards. Then in the screening process, if EPA finds a use that doesn't pose a particular risk, it can be removed so that analysis can be done further on other uses. Is this correct?

**Tala Henry:** Problem formulation is a critical step and understanding the full picture from sources (uses) to outcomes (risk) is needed, which is why EPA is assessing all conditions of the use for each chemical.

**Jamie Conrad, CPMA:** Does EPA want to look more closely at aquatic toxicity because the current screening data shows that there is risk?

**Tala Henry:** Not necessarily; EPA needs to examine the lab study reports as part of systematic review of data that may be useful for risk assessment. EPA

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**Robert Mott, Sun Chemical:** Retrieving and delivering the data that EPA is asking for would involve cooperation with several different affiliates. It would be helpful to have a sense of prioritization in what EPA considers high value so that we can go to those affiliates with some direction.

**Tala Henry:** EPA is attempting to do a comprehensive risk analysis and therefore would need to see all available data.

**Jamie Conrad, CPMA:** There is language in the statute that says EPA does not need to do an in-depth study on each end-point of the chemical.

**Tala Henry:** EPA would need to see the existing studies to make a determination, during problem formulation, on whether an in-depth study is necessary.

**Robert Mott, Sun Chemical:** It seems a decision by a third party was sufficient to be put on the screening list, but is not sufficient for EPA to make a judgment.

**Tala Henry:** EPA used readily available information for the screening process (as described by the methodology that was publicly vetted) and now needs to look at the data if it is to be used in risk assessment.

**Glenn Merritt, CPMA:** There was a study done on Violet 29 as a food additive for FDA. FDA did a risk analysis and determined there was no risk. Would this be sufficient for EPA? In addition, this industry has no information that would indicate significant concerns with Violet 29.

**Tala Henry:** I don't have knowledge of this FDA study. EPA would not necessarily have data for something specifically developed for a food use.

**Jamie Conrad, CPMA:** I would think a federal assessment of risk would hold more merit to EPA. It seems unlikely that there are unknown harmful risks if FDA approved it as low risk in a food additive.

**Tala Henry:** EPA does consider analyses conducted by other Federal Agencies as well as other competent authorities. Did CPMA provide this data to FDA? If so, can it be sent to EPA as well?

**Robert Mott, Sun Chemical:** If FDA used that data, could it not be shared across agencies?

**Steve Camenisch, BASF:** FDA would have some of the data, but not all of it.

**Jamie Conrad, CPMA:** We have initiated a process to get the data that EPA is requesting.

**Tala Henry:** To reiterate, EPA needs the individual studies in order to perform review and evaluation for use in risk assessment.

**Glenn Merritt, CPMA:** Violet 29 is almost completely insoluble. All available data indicates solubility below 10ppm.

**Tala Henry:** That sounds consistent with what EPA has been told, but that needs to be confirmed by the data.

**Steve Camenisch, BASF:** These studies are expensive are owned by various companies. Can they be submitted as CBI?

**Tala Henry:** They can be, but I encourage you not to do so as much as possible to ensure transparency.

**Jamie Conrad, CPMA:** The statute doesn't require that the risk assessment be based on public data, right? This is a matter of getting the data in a timely manner.

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**Tala Henry:** Not explicitly, however, understanding all of the conditions of use is the first step in creating a conceptual model. The uses flow into exposure pathways. Once we get beyond the scoping stage, which covers what will be included in the risk assessment, that is when we delve into the data.

**Joel Wolf:** At this stage, EPA is looking at all uses, whether they are foreseeable, outdated, minimal, etc. because that is what the statute requires.

**Tala Henry:** The scoping documents must be released by June 19, 2017. If EPA doesn't have data before the scope is published to rule out certain in-depth analyses, it could end up being broader than necessary.

### Use Information on Pigment Violet 29:

**Joel Wolf:** Pigment Violet 29 is one of the first ten chemicals under TSCA and EPA is in the process of gathering all uses. EPA has been spending the last several months meeting with various stakeholders and doing research to find uses and conditions of use. Our understanding of the universe of uses is posted in the docket. EPA would appreciate any feedback on how well it captures uses and any other information that could inform the risk evaluation process. We recognize that the time frame is short, but the time schedule for the first ten chemicals were shortened because of the statute. Hannah Braun has been doing the majority of work on Pigment Violet 29 uses. We hope CPMA can say whether those uses have been captured accurately.

**Hannah Braun:** It would be useful to know which uses are predominant in the U.S. and at which volume.

**Robert Mott, Sun Chemical:** Some of these uses from Nordic countries are strange.

**Hannah Braun:** Our research branched out into other western countries due to lack of detailed information in the U.S.

**Robert Mott, Sun Chemical:** The estimated amount of the chemical that is released into commerce is greatly overstated in this docket. We think that it is due to not factoring in that about 80% of it is consumed on-site and never leaves the facility.

**Jamie Conrad, CPMA:** The docket states that there are 4 U.S. manufacturers, but there is only 1. The other sites are processors.

**Robert Mott, Sun Chemical:** It looks like there are 4 companies in the CDR, but it's actually the same facility and equipment that has changed owners multiple times. It's the same physical building and operations. The procedure for manufacturing is well captured. It has not changed since it was developed before WWII.

**Steve Camenisch, BASF:** Of the 20% that leaves the facility, 35% of that leaves North America and therefore does not show up in the uses. This docket does not incorporate internal consumption into its numbers, so the volume is overestimated. Pigment Violet 29 is used to make other pigments such that it is completely transformed in the process.

**Dave Wawer, CPMA:** Sun Chemical is the only U.S. Producer.

**Robert Mott, Sun Chemical:** Of the 65% of the material that is sold in the U.S., 50% of that goes into paint – mostly automobile paint and refinish. It does not go into architectural paint. Slightly less than 1% goes into merchant ink for banners or branding. This could explain why it is seen as an FDA use because FDA requires packaging to be registered. 41% goes into high-performance plastics, such as automobile carpeting and upholstery. The material sold in the U.S.

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constitutes 18 companies. It's currently listed as a range of 100-149 companies. That should be updated in the CDR. This may have occurred because companies change from year to year. So, while there may be only 18-20 companies selling the material in a given year, if there are changes from year to year the cumulative list of companies may be higher.

**Dave Wawer, CPMA:** Lanco Color imports Pigment Violet 29. They would have to report if it was over 25,000 lbs. There could be other chemical distributors that we have no information on if they bring in material from an overseas supplier that's under 25,000 lbs.

**Robert Mott, Sun Chemical:** None of the 18 companies that we sold products to are distributors. Our industry is unique in that we can be competitors as well as suppliers and purchasers to each other, the result being that a product might be sold to a facility and then taken to another site so that the competition doesn't know too much about their use.

**David Wawer, CPMA:** Some of the distributors on EPA's list came from a Google search. Those distributors may not actually have the product on site. As far as art supplies, I am not sure where anyone would get it in the amount of 1 lbs or smaller. There are Chinese manufacturers that are not in our association that could be selling in the U.S. through distributors.

**Robert Mott, Sun Chemical:** The smaller amounts could be from companies that are trying to get into the market that are using sales and marketing reps to solicit businesses. Those would not necessarily be reliable sources.

**Joel Wolf:** At this point, EPA would like to look at the whole universe of uses even if they are determined to be de minimis at a later point.

**Robert Mott, Sun Chemical:** The prices listed in the docket also seem to be incorrect. The price on the bulk material is a clear indicator that they are distributors and not the manufacturers.

**Glenn Merritt, CPMA:** The vast quantity of art materials sources would be controlled by the Arts and Crafts Materials Institute. They have labeling standards and would be a good contact for EPA. They conduct toxicological testing and provide labeling instructions for member companies. Most retail products would be labeled in accordance with that organization.

**Steve Camenisch, BASF:** Textiles are not in the market as much. It's used in very special cases. Printing in general doesn't use it often.

**Robert Mott, Sun Chemical:** Specifications are strict for those materials; companies are more likely to get two other colors and blend them.

**Hannah Braun:** Does CPMA have any insight on whether Pigment Violet 29 is used in spray paint?

**Robert Mott, Sun Chemical:** If it is, it is not a large market. Refinish paints for cars is not usually in the consumer market. In California, the refinish has to be a water-based paint. I don't know where exactly that would be in our supply chain.

**Doug Parsons:** The American Coatings Association might have a better answer.

### Wrap Up:

**Joel Wolf:** It seems the docket did a good job of steering conversation and thought. EPA appreciates CPMA's help in the risk evaluation process.